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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: 1122637

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

April 20, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Paul E. Hicks, President/Owner
Franklin County Respiratory Rentals, Inc.
400 Tanyard Road
Rocky Mount, Virginia 24151

Dear Mr. Hicks:

On April 3, 1998, the Food and Drug Administration (FDA) conducted an inspection of your facility and determined that your firm tranfills Oxygen, U.S.P., which is a drug as defined by Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act).

During the inspection, deviations from the Current Good Manufacturing Practice (GMP) Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed. These deviations, which cause your Oxygen, U.S.P to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, include the following:

1. Failure to adequately test each batch of Oxygen, U.S.P. for conformance to final specifications for the drug product prior to release. Your firm does not calibrate or document the calibration of the oxygen analyzer according to the manufacturer's directions.

2. Failure to adequately calibrate the oxygen analyzer in accordance with the manufacturer's instruction manual. Your firm fails to document the low end calibration of the analyzer.

3. Failure to assure that each person engaged in the transfilling of compressed medical oxygen has the education, training, or experience to enable that person to perform the assigned function. Your firm failed to establish an adequate training program addressing both on-the-job and GMP training.

4. Failure to perform the annual calibration of the pressure gauge used during transfilling of Oxygen, U.S.P.

5. Failure to perform adequate pre-fill, fill, and post-fill operations on each high-pressure cylinder filled. Temperature monitoring of cylinders during filling and vacuum testing prior to filling is not always performed and/or documented.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. A list of observations (FDA-483) was presented to and discussed with Betty Staples, Director of Quality Management, at the close of the inspection. A copy of the FDA-483 is enclosed. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Wiley T. Williamson, III. Mr. Williamson can be reached at (410) 962-4366, extension 136.

Sincerely,

ELAINE KNOWLES COLE
District Director

Enclosure

cc: VA Board of Pharmacy
6606 West Broad Street
Richmond, Virginia 23230-1717